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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/287,884	04/07/1999	HAROLD J. WANEBO	58463/JPW/EM	6824

7590 09/13/2006

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EXAMINER	
ANDERSON, JAMES D	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 09/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/287,884	WANEBO ET AL.	
	Examiner	Art Unit	
	James D. Anderson	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed February 16, 2006, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Status of the Claims

Claims 20-33 are currently pending and are the subject of this Office Action. Claims 20, 23, 25, 28 and 30-31 are presently amended.

Claim Rejections - 35 USC § 112 – Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20-29 and 31-33 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 20, 25 and 31 recite the limitation wherein "an effective amount" is administered to cells, tumors or subjects afflicted with cancer, respectively. This limitation is indefinite because it is not clear what the amount being administered is effective for. Amending the claims to recite a "therapeutically effective amount" would overcome this rejection provided there is

support in the specification for such an amendment. Claims dependent from claims 20, 25 and 31 are included in this rejection.

Claim 22 recites the limitation wherein the cell of claim 20 (*e.g.* leukemic cell, prostate cancer cell, pancreatic cancer cell, squamous carcinoma cell, breast carcinoma cell, myeloid leukemic cell or colon carcinoma cell) is present "in a subject." Claim 22 is indefinite because it is not clear that the subject being administered the agents of claim 20 is in need of such administration. Further, as claim 20 is drawn to a method of increasing apoptosis of a single cell, it is not clear how applicants intend to target administration to a single cell present in a subject.

Claims 23 and 28 contain the trade name "CREMOPHOR." Examiner notes that CREMOPHOR® is a registered trademark of BASF Pharma Solutions. M.P.E.P. § 2173.05(u) states, "It is important to recognize that a trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus a trademark or trade name does not identify or describe the goods associated with the trademark or trade name." If the trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. § 112, second paragraph. *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). Applicant's amendments filed February 16, 2006 still recite a trademark in the claims.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 20, 25, 26 and 30-33 are again rejected under 35 U.S.C. § 103(a) as being unpatentable over Jayadev *et al.* in view of Mycek *et al.* for the reasons set forth in the Office Action mailed 11/14/2005.

Applicant's arguments have been fully considered but they are not persuasive. Applicants argue, *inter alia*, that the references do not support a *prima facie* case of obvious because there is no reasonable expectation of success. Applicants argue that without experimentation, one of ordinary skill cannot reasonably predict a successful anticancer outcome with a particular combination of two drugs. This argument is not persuasive, however, because the standard for 35 U.S.C. § 103 rejections is a *reasonable expectation* of success. The requisite standard is therefore completely independent from any required testing *per se*. As such, examiner maintains that the combination of C_6-ceramide and paclitaxel would have been *prima facie* obvious, as both agents were known in the art to be useful in the treatment of cancer. The skilled artisan, absent any testing, would have had a *reasonable expectation* that the two compounds would be effective in treating cancer when administered together. Thus, a *prima*

facie case of obviousness has been established and the rejection of claims 20, 25, 26 and 30-33 is maintained.

Claims 20-33 are again rejected under 35 U.S.C. § 103(a) as being unpatentable over Spencer *et al.* in view of Cai *et al.* for the reasons set forth in the Office Action mailed 11/14/2005.

Applicant's arguments have been fully considered but they are not persuasive. Applicants again argue that the references do not support a *prima facie* case of obvious because there is no reasonable expectation of success. Applicants argue that without experimentation, one of ordinary skill cannot reasonably predict a successful anticancer outcome with a particular combination of two drugs. As discussed *supra*, this argument is not persuasive because the standard for 35 U.S.C. § 103 rejections is a *reasonable expectation* of success. The requisite standard is therefore completely independent from any required testing *per se*. Examiner again maintains that the combination of C_6-ceramide and paclitaxel would have been *prima facie* obvious, as both agents were known in the art to be useful in the treatment of cancer. The skilled artisan, absent any testing, would have had a *reasonable expectation* that the two compounds would be effective in treating cancer when administered together. Thus, a *prima facie* case of obviousness has been established and the rejection of claims 20, 25, 26 and 30-33 is maintained.

With regard to the above rejections, given the state of the art the skilled artisan would reasonably expect a synergistic effect in the reduction of apoptosis and/or the treatment of cancer

using a combination of paclitaxel and C_6-ceremide. The synergistic effects demonstrated in the examples cannot overcome a *prima facie* case of obvious because these results would be expected. Paclitaxel is known to block cell growth in the G_2-M phase of the cell cycle, whereas ceramide blocks cells in a different phase of the cell cycle (G_0-G_1). One of ordinary skill in the art would expect that apoptosis and inhibition of cell proliferation would be greater with a combined treatment than with either agent administered alone because paclitaxel and C_6-ceremide exert their effects at different points in the cell cycle.

With regard to the Joshi *et al.* in view of Hartfield *et al.* rejection of claims 20, 22-25 and 27-31, although Joshi *et al.* teach the administration of PEG-ceramides, they do not disclose the administration of ceramide or C_6-ceramide. In the absence of a teaching of the equivalence of PEG-ceramides and ceramide or C_6-ceramide, the reference does not teach all of the limitations of the instant claims. As such, applicant's arguments are persuasive to overcome this rejection. The rejection of claims 20-33 in view of Joshi *et al.* and Hartfield *et al.* under 35 U.S.C. § 103 has been **withdrawn**.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James D. Anderson whose telephone number is 571-272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

James D. Anderson
Patent Examiner
AU 1614

August 31, 2006

Ardin H. Marschel 9/4/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER